

Office of Surveillance and Epidemiology Program Description

Pharmacists' Role in Communicating Safety at the FDA Pharmacy Student Experiential Program Office of Surveillance and Epidemiology Outreach and Communications Team

Purpose

Medication safety is a critical component of a pharmacist's training. At the FDA pharmacy students can learn and apply the principals of safety by experiencing them first hand through interactions with the various offices in the Agency.

The pharmacist has a unique public health responsibility to communicate drug safety issues in a timely and assessable manner that is reassuring and easy to understand. A pharmacist may be the only professional with a complete medication profile and the last safety check between the patient and a prescription drug.

This program will introduce the pharmacy students to the Role of Pharmacists in Communicating Safety at the FDA. Communicating drug safety and risk is a difficult balance the FDA struggles with daily. To protect the public health of U.S. citizens, the Agency must make the best decisions with science and data made available to them and communicate this information to the public in the most transparent way possible.

The goal of this program is to educate pharmacy students with little experience in public health about how the FDA communicates drug safety and protects the public health of our nation.

Learning Objectives

1. Understand the role of pharmacist at the FDA in communicating safety issues.
2. Assist in writing a Drug Safety Communication (DSC).
3. Understand the path of a DSC from discovery of safety event to public communication.
4. Discuss challenges the MedWatch reporting program faces.
5. Suggest methods to increase reporting of adverse drug events.
6. Explain the different roles of the trade press office and the FDA Press office.
7. Learn about alternative pharmacy career options.

The following table lists examples of how the above objectives may be met and the associated activities during a given rotation in OCT.

Final Requirements

1. Complete and submit a brief article for publication in AJHP or other pharmacy/medical journals on any aspect of the rotation.
2. Complete a final evaluation of the program.

Students are strongly encouraged to present their work as a poster at a community or school event and/or local, state or national pharmacy meeting. The poster can be completed during the rotation.

Objectives and Activities

FDA Office/POC	Objective	Activity
<u>Office of Surveillance and Epidemiology</u> (OSE) OutReach and Communications Team	Become familiar with the methods of communicating drug safety in each division of the office	<ul style="list-style-type: none"> ·Work closely with Outreach and Communication Team (OCT) to process daily work—Drug Safety Communications (DSC), press inquiries, EMA video-cons, 4-way t-cons, GAOs, DSaRM, public meetings ·Hands-on experience with DSCs working with professionals in the office generating responses ·Work with other OSE divisions to understand their role in communicating drug safety to public ·Attend safety seminar, center briefing, etc
<u>Office of Communication</u> (OCOMM) Laura Pincock Sheilyn Haung	Understand how to communicate a drug safety issue from planning stage to public communication	<ul style="list-style-type: none"> ·Assist in developing safety communications for public ·Draft a DSC, internal Q&A, press release ·Attend a media call
<u>FDA Press Offices</u> Karen Reily <u>CDER Press Office</u> Julie Zawisza	Observe and compare FDA messaging with large media outlets vs. professional journals	<ul style="list-style-type: none"> ·Observe interaction with reporters ·Attend a press conference ·Attend an interview with a national outlet
<u>MedWatch</u> Anna Wojas Brenda Rose	Follow the path of MedWatch report from event to DSC	<ul style="list-style-type: none"> ·Visit data entry center ·Discuss program with Anna Wojas, X68471 ·Discuss ideas for project?
<u>Advisors and Consultants</u>	Become familiar with the role of the Drug Safety and Risk Management Advisory Committee in protecting the U.S. public health	<ul style="list-style-type: none"> ·Attend a DSaRM Advisory Committee (AC) meeting ·Discuss the COI(conflict of interest) process for meeting ·Learn about the steps leading to AC meetings ·Discuss AC results from FDA's perspective (e.g. Avandia) and next steps
<u>Pharmacy Association Visits</u>	Recognize the importance of ongoing membership in a professional association	<ul style="list-style-type: none"> ·Attend visits with other FDA externs ·Discuss the role of professional associations working with FDA to communicate safety
<u>Safe Use</u> (Optional)	Become aware of the goals and objectives of the program	<ul style="list-style-type: none"> ·Orientation by Safe Use staff ·Attend listening sessions or other stake holder meetings ·Make suggestion for a Safe Use project
<u>OC/Office of External Affairs</u>	Observe high level FDA program rollout	<ul style="list-style-type: none"> ·Participate in planning and roll out of program

(Optional)		
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